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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,777	MARSHALL, ROBERT J.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-22 and 24* is/are pending in the application.

4a) Of the above claim(s) *13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12, 20-22 and 24* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This Office Action is in response to the Applicant's reply received 8/19/08. Claims 4-22, and 24 are pending. Claims 13-19 are withdrawn. Claims 1-3 and 23 are cancelled. Claims 4-10, 13, 16, 17, 18, 20-22, and 24 have been amended. No claims are new.

Response to Applicant's Amendments

Claim Objections

Claim 24 is objected to for having misspelled "harvestable".

New Rejections Necessitated by Applicant's Amendment

The following rejections are made in response to the Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-12, 20-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for claiming new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claims 4, 21 and 24 contain the limitation "harvestable quantity". The Examiner found no support in the as-filed specification for the definition of "harvestable quantity" or any guidance to determine such a quantity. Also the limitation does not clearly

indicate that the **DHLA** (dihydrolipoic acid) is isolated or purified, simply “harvested" and as such considering the broad-use of the term harvested, simply collecting DHLA containing microorganisms will read on "harvested…naturally-derived dihydrolipoic acid” since the DHLA is inherently collected with the micro-organisms. In the interest of compact prosecution the Examiner will interpret the value for "harvestable quantity" as any quantity of DHLA present in the composition.

Response to Applicant's Arguments

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claim 4-10, 12 and 18, 20-22 is withdrawn in light of the Applicant’s amendments that remove the term “stabilized” and corrected the dependency of claim 22.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 4-10 and 20-22 over Hastings et al. in view of Hermann et al. with additional support by Pyruvate Dehydrogenase & Krebs Cycle and Reed were considered but not found persuasive.

Applicant argues that their invention is “a composition that acts as a microbiological culture medium in which the probiotic organism(s) produce an excess amount of DHLA that can be harvested for use in a dietary supplement for human consumption” (Applicant’s Response, pg 10, 1st Full paragraph). Firstly, this argument is not commensurate with the scope of the claims. The claims are to a composition of

at least one live stabilized DHLA producing probiotic organism, b) R-Lipoic acid, and c) at least one nutritive agent where the composition produces a harvestable quantity of DHLA. As mentioned above the "harvestable quantity" of DHLA is interpreted as any amount of DHLA in the composition whether isolated or not. The claims do not limit that the DHLA is made in excess amounts, furthermore the Applicant has not defined what are "excess amounts" and how the currently cited art does not read on such amounts.

Secondly, as mentioned in the previous Office Actions claims 4, 21, and 24 are to compositions comprising DHLA producing microorganisms and not methods of producing DHLA. Compositions are limited by their structure and not their intended uses such as a "microbiological culture media". However the prior art cited by the Examiner teaches it would be obvious to one of ordinary skill in the art to make a composition with the same structural components of the instant compositions. Therefore any inherent property of such a compositions is also obvious.

In the instant case, Applicant alleges that the prior art composition does not obviate the instantly claimed composition, because the instantly claimed composition is claimed for use as microbiological culture media, while the prior art composition is described for use as a dietary supplement. The *Schreiber* court wrote, "A patent applicant is free to recite features of an apparatus either structurally or functionally…[but] choosing to define an element functionally, *i.e.*, by what it does, carries with it a risk. As our predecessor court stated in *Swinehart*, 439 F.2d at 213, 169 USPQ at 228: 'where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact,

be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" See *In re Schreiber*, 128 F.3d at 1478, 44 USPQ2d at 1432, and M.P.E.P. § 2112. Even though the prior art composition is not specifically taught as being useful for Applicant's claimed intended use or application, *i.e.* microbiological culture medium, it obviates the currently claimed invention, absent a substantive evidentiary showing that the prior art composition could not be employed for the instantly claimed intended use.

The Applicant argues that Hastings and Hermann do not teach that their dietary supplements "produce an excess of naturally-derived DHLA that can be harvested and used for a separate purpose" (Applicant's Response, pg 10, last full paragraph). However as mentioned above, this argument is not commensurate with the scope of the claims since there are no limitations that state the DHLA is "harvested...for a separate purpose". Furthermore any active steps that include harvesting or isolating the DHLA would be read as product by processes and given little patentable weight in a composition (M.P.E.P. § 2113).

In summary, since the prior art previously cited teach all the components of the composition as claimed they are obvious regardless of the intended use of the composition. This rejection can be overturned if evidence is provided that shows the composition cited by the Examiner could not be used for the same purpose within the scope of the claims. The Applicant is reminded that broad terms and amounts such as "harvestable quantity" are given their broadest reasonable interpretation to one or

ordinary skill in the art. As such, unless evidence is provided to the contrary, "harvestable quantities" can read on infinitesimal amounts given the state of the art of separations with tools such as HPLC and Ion Exchange as well as other such chromatography.

Therefor the rejection(s) stand and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-10 and 20-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent # 6368617) in view of Hermann et al. (European Journal of Pharmaceutical Sciences, 1996) with additional support provided by Pyruvate Dehydrogenase & Krebs Cycle (1998) and Reed (JBC, 2001).

These claims 4-10 are drawn to a microbiological broth comprising three parts a) at least one live stabilized dihydrolipoic acid producing probiotic organism, b) R-Lipoic acid, and c) at least one nutritive agent. The probiotic organism can be from *Lactobacillus*, *Bifidobacterium*, *Enterococcus*, *Streptococcus thermophilus*. More specifically the microorganisms can be selected from the group consisting of: *L. acidiophilus, L. paracasei, L. fermentum, L. rhamnosus, L. johnsonii, L. plantarum, L. reuteri, L. salivarius, L. brevis, L. bulgaricus, L. helveticus, L. grasseri, L. casei, L. lactis, B. bifidum, B. breve, B. infantis, B. longum, B. lactis, E. faecium,* and *E. faecalis*.

Claim 21 is an additional composition comprising *B. longum, L. acidiophilus, E. faecium, Streptococcus thermophilus* and R-Lipoic acid, and at least one nutritive agent. Claim 22 depends from claim 21 and further comprises *B. breve, B. infantis, L. casei, L. fermentum, L. helveticus, and L. plantarum.*

Claim 20 depends from claim 4 and further limits that the probiotic organism for use in a medicament or a nutritional supplement.

Hastings et al. teach a composition in claim 11 (col 7) comprising a probiotic blend of *B. bifidum* and *L. acidophilus*, a nutrient substance such as omega-3 fatty acids and saccharides, and can further comprise alpha-lipoic acid (claim 15, col 8). This composition can be formulated into a liquid broth (Example 1). While Hastings does not teach solely the (R) enantiomer of lipoic acid, it is obvious to use this enantiomer from the teachings of Hermann et al.

Herman et al. teach that of the racemic forms of alpha lipoic acid, the (R) enantiomer has greater bioavailablity than the (S) enantiomer (Abstract, last 3 lines). One of ordinary skill in the art that knew of the teachings of Hermann et al. would recognize using the enantiomerically pure (R) form of lipoic acid would improve the composition of Hastings et al. The motivation is provided by Hastings et al. who show that the bioavailability of R-lipoic acid is superior to S-lipoic acid. The reasonable expectation of success is provided by Hastings et al. who show that the composition which already includes R-lipoic in a racemic mix with S-lipoic acid can be formulated.

Hastings et al. also does not teach a composition containing all the bacteria listed in claims 21 or 22. However these bacteria are well known in the art as probiotic

bacteria as supported by Mercenier et al. (Current Pharm. Design Jan. 2003) and Dunne et al. (Antonie van Leeuwnhoek, 1999). Hastings et al. already uses a probiotic blend of *B. bifidum* and *L. acidophilus*. According to M.P.E.P. § 2144.06:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Since Hastings et al. already adds a probiotic blend to their composition it would be *prima facia* obvious to add other probiotic organisms to their invention. Therefore claims 4-10 and 20-22 remain *prima facia* obvious over Hastings et al. in view of Hermann et al.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 11 and 12 over Hastings et al. and Hermann et al. as applied to the rejections of claims 4-10 and 20-22 above and in further view of Reddy et al. were considered but not found persuasive.

Applicants rely on the arguments used in traversing the above rejection to also traverse this rejection without additional arguments. However, as explained above, the previous rejection stands. Therefore, the response set forth above to arguments also applies to this rejection as well as new claim 24.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 12 remain rejected and new claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. and Hermann et al. as applied to the rejections of claims 4-10 and 20-22 above and in further view of Reddy et al. (U.S. Patent # 6,080,401).

These claims further limit the composition of claim 4 by including turmeric rhizome (*curcuma longa*) as the nutritive agent. Also claim 24 adds the limitation that the probiotic organism converts R-lipoic acid via incubation.

As mentioned in the reference above, Hastings et al. in view of Hermann et al. teach a composition that comprises at least one live probiotic organism, R-lipoic acid and a nutritive agent. The two references with the support from Reed and Pyruvate Dehydrogenase & Krebs Cycle teach that DHLA is indeed produced from R-lipoic acid in the α-keto oxidation process of the probiotic. However these two references do not specifically teach the addition of *curcuma longa* to their composition. This is taught by Reddy et al.

Reddy et al. teach a composition that, like Hastings et al., includes a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col 9, lines 33-44) to assist in weight loss and dieting (col 4, line 12), which is the same reason as Hastings et al. Reddy et al.

also adds *Curcuma longa* to the composition (col 8, line 5) as a hepatic stimulant. It would have been obvious to someone skilled in the art to add *Curcuma longa* to the composition of Hastings et al. since both inventions share a common goal for a composition to assist in a diet and also share common materials such as a probiotic blend (see M.P.E.P. § 2144.06).

While the art above teaches the components of the composition of claim 4 they do not teach the amounts limited by claim 12. However, M.P.E.P. § 2144.05 II states:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the composition of claim 4, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts listed in claim 12 are result effective variables whose ratio and concentration are a matter of routine optimization.

Therefore claims 11, 12 and new claim 24 remain *prima facia* obvious over Hastings et al. and Hermann et al. in view of Reddy et al.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651